FOOT ORTHOSIS FOR PATIENTS WITH DIABETIC FOOT ULCER

By:

KANG JING YONG

(Matrix no: 125016)

Supervisor:

Dr. Mohamad Ikhwan Zaini Ridzwan

MAY, 2018

This dissertation is submitted to

Universiti Sains Malaysia

As partial fulfillment of the requirement to graduate with honors degree in

BACHELOR OF ENGINEERING (MECHANICAL ENGINEERING)



School of Mechanical Engineering Engineering Campus Universiti Sains Malaysia

Declaration

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

Signed...... (KANG JING YONG)
Date.....

STATEMENT 1

This thesis is the result of my own investig	gations, except where otherwise stated. Other sources
are acknowledged by giving explicit reference	ences. Bibliography/references are appended.
Signed	(KANG JING YONG)
Date	

STATEMENT 2

I hereby give consent for my thesis, if accepted, to be available for photocopying and for

interlibrary loan, and for the title and summary to be made available outside organizations.

Signed...... (KANG JING YONG)

Date.....

Acknowledgement

Firstly, I would like to express my sincere gratitude to my supervisor, Dr. Mohamad Ikhwan Zaini Ridzwan for his continuous supervision and assistance from the beginning stage until the end stage of this project. This dissertation is not possible without his willingness to provide guidance, encouragement and suggestions throughout the whole period.

Besides, I would also like to thank to the School of Mechanical Engineering for allowing me to use the 3D scanner available in the school for this project. I also will like to sincerely thank the assistance engineer, Mr. Norijas Abdul Aziz for the given knowledge regarding the use of the 3D Scanner. This knowledge was extremely valuable for me to proceed further in this project.

Moreover, I would like to express my gratitude to my family. They always give me support and encouragement to me spiritually and mentally. In addition, I will like to thank my coursemates for their generosity in sharing their knowledge and ideas in the construction of this project.

I wish to also express my gratitude to the speaker of the Thesis writing workshop, Assoc. Prof. Ir. Dr. Abdus Samad Mahmud for giving me a guideline on how to write the thesis from beginning until the end. This guideline is extremely valuable for me to write this thesis in accordance to international standards. Last but not least, I will also like to express my gratitude to the coordinator of the Final Year Project, Dr. Mohamad Ikhwan Zaini Ridzwan for his effort in arranging the schedule of this course, organizing workshops regarding to thesis writing and keeping the progress of final year project on track. I also had perceived this project as a stepstone for my career development. I will strive to my best to use the skills and knowledge gained from this project and I will continue to work on their improvement, in order to attain the desired career objectives.

Table of	Contents
-----------------	----------

Declarationi
Acknowledgementii
Table of Contents iii
List of Figuresv
List of Tables
List of Abbreviations
Abstrakix
Abstractx
Chapter One: Introduction
1.1 Research Background1
1.2 Problem Statement
1.3 Objectives
1.4 Thesis Outline
Chapter Two: Literature Review
2.1 Introduction
2.2 Structure of a Human Foot
2.3 Lower Extremity Ulcers
2.3.1 Types of Lower Extremity Ulcers
2.3.2 Classification of Diabetic Foot Ulcers
2.4 Gait Cycle
2.4.1 Phases of a Gait Cycle
2.4.2 Plantar Pressure
2.4.3 Plantar Pressure Measurement
2.5 Finite Element Method of the Foot
2.5.1 Recent works on FE of the Foot
2.5.2 Generation of 3D Foot Models15
2.6 Treatment for Diabetic Foot Ulcer
2.6.1 Off-loading Techniques
2.6.2 Insole of Foot Orthosis
Chapter Three: Research Methodology
3.1 Introduction

3.2 Sample Preparation	20
3.2.1 Creation of a Mould	20
3.2.2 Creation of a Sculpture	22
3.3 3D Scanning	24
3.4 Generation of Digital Model	27
3.5 Finite Element Method for the Foot Models	28
3.5.1 Generation of 3D Models	28
3.5.2 Defining Contact Problem between 3D Foot Models	30
3.5.3 Materials Properties of the Finite Element (FE) Model	31
3.5.4 Loading and Boundary Conditions of the FE Model	33
Chapter Four: Result and Discussion	34
4.1 Introduction	34
4.2 Mesh Convergence Study	34
4.3 FE Validation with Previous Works	38
4.3.1 Peak and Distribution of Plantar Pressure	39
4.3.2 Regional of Peak Plantar Pressure	41
4.4 FE Predictions of Diabetic Foot Ulcer	43
4.4.1 Comparison between Healthy Foot Model and Ulcer Foot Models	43
4.4.2 Effect of Ulcer Sizes to Peak Plantar Pressure	46
4.4.3 Effect of Peak Plantar Pressure to the Location of Ulcer Formation	48
4.4.4 Performance of Different Materials for Foot Orthosis's Insole to the Foot Models	49
Chapter Five: Conclusion and Recommendation for Future work	53
5.1 Conclusion	53
5.1.1 Plantar Pressure Distribution of a Diabetic Foot Ulcer	53
5.1.2 Effect of Peak Plantar Pressure with the Presence of Ulcer	53
5.1.3 Most Effective Material for Insole of a Foot Orthosis	54
5.2 Recommendation for Future Works	54
References	55
Appendices	59

List of Figures

Figure 2.1: The three sections of human foot [12]
Figure 2.2: Anatomy of human foot in lateral view [13]
Figure 2.3: Types of lower extremity ulcers a) Neurotrophic ulcer b) Venous stasis ulcer c) Arterial
ulcer [14]
Figure 2.4: The Wagner classification of diabetic foot ulcers [17]7
Figure 2.5: The University of Texas classification of diabetic foot ulcer [17]
Figure 2.6: The phases of a gait cycle a) Sub-phases of stance phase b) Sub-phases of swing phase
[21]
Figure 2.7: The normal gait cycle of human during locomotion [21] 10
Figure 2.8: In-shoe plantar pressure measurement for a full gait cycle (right heel strike to right
heel strike). HS = heel strike, FF = foot flat, MSt = midstance, HO = heel off, TO = toe off, IS =
initial swing, MSw = midswing. [20]
Figure 2.9: Location of DFU a) Plantar pressure distribution of a human foot [22] b) Ulcer at 1 st
metatarsal region c) Ulcer at heel region
Figure 2.10: Pressure sensing technologies a) Platform systems b) In-shoe systems [23]
Figure 2.11: Foot modelling using medical imaging techniques [29] 15
Figure 2.12: Foot modelling using 3D surface scanning method [31] 16
Figure 2.13: Different types of off-loading techniques a) Foot orthosis [34] b) Total contact cast
[35] c) Rear foot off-loading shoe [36]17
Figure 2.14: Two commonly used materials for developing foot orthoses a) Plastazote foam [39]
b) Poron foam [40]
Figure 2.15: The performance of Poron in cushioning application
Figure 3.1: The use of alginate powder in the mould creation stage to capture the complex shape
of foot [44]
Figure 3.2: The created mould of the right foot sample to be used in the creation of the foot
sculpture
Figure 3.3: The use of Plaster of Paris powder to create the sculpture of human foot sample [45]
Figure 3.4: The foot sculpture of the right foot sample which has a dimension of 90 mm width
and 230 mm height

Figure 3.5: Components available in the Next Engine Desktop 3D Scanner
Figure 3.6: The distance of the stand from the 3D scanner is set to 400 mm to ensure the entire
view of the foot sculpture can be seen
Figure 3.7: The scan image of the foot sculpture in .igs file format
Figure 3.8: The process of generating the digital model of the foot sculpture a) The generated
mesh model from the scanned file in .igs file format b) The generated 3D surface foot model in
.step file format
Figure 3.9: 3D solid body of the healthy foot model
Figure 3.10: 3D solid body of foot ulcer at a) 1 st metatarsal region b) heel region
Figure 3.11: The boundary and loading conditions applied to the FE models a) Foot models
without insole b) Foot models with insole
Figure 4.1: The Region of Interests (ROIs) used for the mesh convergence analysis a) ROI 1, the
area around 1 st metatarsal region b) ROI 2, the area around heel region
Figure 4.2: Selection of best number of elements for ROI 1
Figure 4.3: Graph of average stress for ROI 2 against number of elements
Figure 4.4: Graph of computational time against the number of elements
Figure 4.5: Selected regions for the FE analysis of the 2 nd aspect
Figure 4.6: Comparison of peak plantar pressures at different foot regions using different foot
orthosis materials
Figure 4.7: Selected region for the FE analysis of the 2 nd aspect
Figure 4.8: Ulcer sizes effect to peak plantar pressure
Figure 4.9: Selected regions for the FE analysis of the 3 rd aspect
Figure 4.10: Peak plantar pressure at different foot regions for different simulated ulcer location
Figure 4.11: Selected regions for the FE analysis of the 4 th aspect for a) healthy foot model b) foot
model with an ulcer at 1 st metatarsal region c) foot model with an ulcer at heel region
Figure 4.12: Peak plantar pressure reduction at different foot location using different insole
materials for a) healthy foot model b) foot model with an ulcer at 1 st metatarsal region c) foot
model with an ulcer at heel region

List of Tables

Table 3.1: The thickness for different skin layer of the foot [46]
Table 3.2: The contact regions defined for the 3D foot models 30
Table 3.4: Materials properties of the FE model
Table 3.5: The coefficients of hyperfoam material model used for the insole materials [27] 32
Table 4.1: The average stress for ROI 1 and ROI 2, and computational time against different
element sizes
alement sizes.35 Table 4.2: Comparison between the plantar pressure distributions of FE analysis with various
element sizes. 35 Table 4.2: Comparison between the plantar pressure distributions of FE analysis with various literatures. 40
element sizes. 35 Table 4.2: Comparison between the plantar pressure distributions of FE analysis with various literatures. 40 Table 4.4: Comparison between the healthy foot model and the ulcer foot models. 45

List of Abbreviations

3 Dimensional
Computer Aided Design
Centre of Pressure
Diabetic Foot Ucer
Diabetes Melitus
Ethylene Vinyle Acetate
Finite Element
Region of Interest

Abstrak

Ortosis kaki kebiasaannya digunakan oleh pesakit diabetes untuk melegakan kesakitan dan mengelakkan pembentukan ulser. Orthosis kaki boleh dibuat daripada pelbagai bahan yang mempunyai tahap kekerasan, kawalan dan kesesuaian yang berbeza.

Kajian ini melibatkan perbandingan lima bahan lapik dalam yang terpilih iaitu Poron_L24, Poron_L32, Nora_SLW, Nora_SL dan Nora_AL untuk analisis tiga dimensi (3D) unsur terhingga (FE) bagi ketiga-tiga model kaki, penentuan kesan puncak tekanan plantar dengan kehadiran ulser, dan siasatan sama ada analisis FE untuk sebuah 3D reka bentuk berbantu komputer (CAD) model kaki manusia yang dihasilkan daripada pengimbas 3D boleh digunakan untuk meramalkan pembahagian tekanan plantar pada ulser kaki diabetik. Kesemua kajian ini telah dijalankan mengunakan ANSYS 16.0. Sementara itu, model 3D kaki untuk analisis FE telah diperoleh menggunakan sebuah pengimbas 3D setelah menyediakan sebuah sampel kaki manusia.

Daripada analisis FE, Poron_L24 telah ditentukan sebagai bahan yang paling berkesan dalam mengurangkan puncak tekanan plantar bagi kesemua tiga model kaki (15.96% untuk model kaki yang sihat, 29.82% untuk model kaki dengan ulser pada kawasan tulang metatarsus yang pertama dan 33.17% untuk model kaki dengan ulser di kawasan tumit). Oleh itu, analisis ini telah menunjukkan bahawa bahan lapik dalam yang lembut dan cell busa yang terbuka dapat mengurangkan tekanan plantar paling banyak pada kaki.

Selain itu, analisis FE telah menunjukkan bahawa kehadiran ulser menyebabkan puncak tekanan plantar pada kaki meningkat secara mendadak sehingga menghampirir 40%. Sebuah kaki dengan ulser pada rantau tulang metatarsus yang pertama telah didapati meningkatkan puncak tekanan plantarnya sebanyak 38.8% manakala kaki dengan ulser pada kawasan tumit telah didapati meningkatkan puncak tekanan plantarnya sebanyak 38.6%.

Tambahan pula, analisis FE CAD model 3D pada kaki manusia telah terbukti mampu meramalkan pengedaran tekanan plantar ulser kaki pesakit diabetes kerana peratusan penyimpangan puncak tekanan plantar daripada kerja sebelumnya ialah di bawah 10% (4.3% untuk Cheung dan 7.6% untuk Tao) dan telah menpunyai perbezaan peratusan sehingga 5% apabila analisis ini telah dibandingkan dengan kaedah yang digunakan oleh Cheung.

Abstract

A foot orthosis is commonly used in diabetic individuals in order to relieve pain and avoid the formation of ulcer. They can be fabricated from a variety of materials which possess different degrees of hardness, control and conformability.

The research involves the comparison of five selected insole materials which are Poron_L24, Poron_L32, Nora_SLW, Nora_SL and Nora_AL for the three-dimensional (3D) finite element (FE) analysis of the three foot models, the determination of the effect of peak plantar pressure with the presence of ulcer, and the investigation whether FE analysis of a 3D Computational Aided Design (CAD) model of human foot generated from a 3D scanner can be used to predict the plantar pressure distribution of a diabetic foot ulcer. All of this studies were done using ANSYS 16.0. Meanwhile, the 3D foot model for the FE analysis was obtained by using a 3D scanner after preparing a human foot sample.

From the FE analysis, Poron_L24 was determined to be the most effective material in reducing the peak plantar pressure for all three foot models (15.96% for the healthy foot model, 29.82% for the foot model with an ulcer at 1st metatarsal region and 33.17% for the foot model with an ulcer at heel region). Hence, it showed that a softer and open cell foam insole material able to reduce the most peak plantar pressure of the foot.

Besides, the FE analysis also showed that the presence of ulcer causes the peak plantar pressure of the foot to drastically increase up to approaching 40%. A foot with an ulcer at metatarsal region was found to have increase the peak plantar pressure by 38.8% while a foot with an ulcer at heel region was found to have increase the peak plantar pressure by 38.6%.

Furthermore, the FE analysis of a 3D CAD model of a human foot was proven to be able to predict the plantar pressure distribution of a diabetic foot ulcer as the percentage deviation of peak plantar pressure from previous works is below 10% (4.3% for Cheung and 7.6% for Tao) and had a percentage difference up to 5% when it was compared with the method used by Cheung.

Chapter One: Introduction

1.1 Research Background

Diabetes Mellitus (DM), commonly referred as diabetes, is a chronic and complicated disease, in which the body either cannot secrete insulin or unable to use the insulin it produces [1]. Insulin is a hormone that regulates the glucose level in the blood. Diabetes usually causes high blood sugar levels, which eventually affects and damage majority of the vital organs in human body [2]. This disease is categorized into two types which are type 1 and type 2.

Type 1 diabetes occurs when the immune system mistakenly attacks and kills the beta cells of the pancreas which secrete insulin, resulting in sugar to be built up in the blood instead of being used as energy [1]. Meanwhile, Type 2 diabetes occurs when the body cannot properly use the insulin or make not enough insulin, causing the same result as Type 1 diabetes [1].

Today, DM is a major public health concern in Malaysia. It was reported that the prevalence rate is on the rise and is predicted that it will increase by a double by 2030 [3]. An uncontrolled DM will lead to many health complications which includes heart disease, blindness and amputation [4]. The most concern complications of DM is diabetic foot ulcer (DFU). This is because patients with diabetes has a lifetime risk as high as 25% to likely to develop a foot ulcer [5]. In addition, limb amputation which is the most expensive and feared consequence of a foot ulcer, occurs 10-30 times more frequently in patients with diabetes compared to the general population [5].

A DFU is defined as a lesion with loss of epithelium, which may extend into the dermis or, in some cases, involve muscles and bones particularly at the lower extremities [6]. They are usually formed at the foot sole when the patient's foot is exposed to prolonged pressure or trauma [7]. Patients with DFU often felt pain because of the increased pressures under their metatarsal heads. This is because there is a relationship between excessive localized pressure and ulceration [8]. Hence, interventions such as foot orthosis that able to relieve the pressure are proposed. In this project, the foot orthosis insole will be the main focus.

1.2 Problem Statement

Information about the magnitude and distribution of plantar pressure is essential to diagnose various foot disorders, particularly DFU. However, measuring this parameter using plantar pressure sensing technologies, which are diversely available, is not effective as each technology produces different results [8]. In addition, the pressure threshold for tissue damage is yet to be known, which could be true for all the sensing technologies [8]. Moreover, modelling a human foot from scratch is difficult because of the complexity of the structure. Hence, the computational approach such as finite element method provides an efficient alternative.

Generally, a 3D anatomical detailed of a human foot is reconstructed from Computerized Tomography (CT) images. This technique involve segmentation process, where bone tissues in each CT images need to be segmented before acquiring the 3D model. As each foot is made up of 28 bones, 30 joints and more than 100 muscles, tendons and ligaments, hence the process can be tedious and time consuming. In addition, CT scanning will expose radiation to the subject. The FE analysis of the 3D foot model can only be performed after the reconstruction process is completed.

Recent biomechanical studies have shown that the mechanical loads acting on the foot in the form of peak plantar pressures are strongly correlated to tissue breakdown in diabetic foot [9]. A high plantar pressure can be reduce through the use of footwear orthosis. A footwear orthosis can be described as shoe insert that able to off-load pressure in areas of the foot that may cause ulceration. These orthoses can be fabricated from a variety of commercially available materials which possess different degrees of hardness, control and conformability However, there is a wide debate among clinicians about whether or not, a softer insole material able to effectively reduce the peak plantar pressure in areas where there is a high risk of an ulcer development [10].

1.3 Objectives

- To investigate whether FE analysis of a 3D CAD model of human foot generated from a 3D scanner can be used to predict the plantar pressure distribution of a diabetic foot ulcer
- 2) To determine the effect of peak plantar pressure with the presence of ulcer by comparing the pressure analysis for an ulcer foot model to a healthy foot model
- To investigate the most effective material for insole of a foot orthosis which is able to significantly reduce the peak plantar pressure

1.4 Thesis Outline

There are five chapters discussed throughout this project. Chapter One narrates the research background related to this project. The problem statement and the objectives of this project are also discussed.

Chapter Two describes about the structure of a human foot, the types of lower extremity ulcers, classification of diabetic foot ulcers, the gait cycle, plantar pressure, other factors that causes diabetic foot ulcer, foot finite element method, of-loading techniques and followed by the insole of foot orthosis.

Chapter Three details the method of preparing the sample. After that, it discusses about the procedure for 3D scanning followed by the method of generating the 3D model. Next, the finite element method is discussed. In this method, the preparation of the solid body, the FE model's properties, the material properties used in the FE model and the loading and boundary condition of the FE model is also elaborated.

Chapter Four discusses the mesh convergence study, the validation of FE model by comparing it with several literature and the findings from the FE analysis in the form of figures, tables and charts.

Chapter Five synthesizes the findings of the study and proposes future works.

Chapter Two: Literature Review

2.1 Introduction

The literature review first introduces the structure of a human foot. After introducing the structure of human foot, the types of ulcers are discussed followed with how diabetic foot ulcers are classified. Next, it describes about the gait cycle. The method of developing the foot finite element and the off-loading technique are also described in this chapter. The insole of foot orthosis was lastly described in this chapter.

2.2 Structure of a Human Foot

The human foot is a strong and complex mechanical structure that is composed of 26 bones (28 if the sesamoids bones on each foot is considered) whose motions are closely interrelated [11]. It generally can be subdivided into three sections namely the hindfoot, the midfoot and the forefoot (Figure 2.1).



Figure 2.1: The three sections of human foot [12]

The hindfoot is consist of the ankle bone (talus) and the calcaneus (heel bone). Together, they forms the heel and ankle. This section helps in weight bearing and articulates with the lower leg bones which are the tibia and fibula [11].

The midfoot section is composed of five irregular bones which is the cuboid bone, the navicular bone and three cuneiform bones. These pyramid-like collection of bones will form the arches of the feet [13]. The mid-foot has two roles. It not only absorbs shock during weight bearing, but it also forms the stability when pushing off to initiate the next step [11].

The forefoot section consist of five toes and the corresponding five proximal long bones forming the metatarsus (metatarsal) (Figure 2.2). Similar to the fingers of a human hand, the bones of the toes are called phalanges. This section provides balance, agility and proprioception [11].



Figure 2.2: Anatomy of human foot in lateral view [13]

2.3 Lower Extremity Ulcers

Lower extremity ulcers are fairly common in diabetic patients, but to completely heal them is a difficult task [7]. Even once they are healed, there is a high possibilities for them to resurface again.

2.3.1 Types of Lower Extremity Ulcers

There are basically three different types of lower extremity ulcers which are neurotrophic ulcer, venous stasis ulcer and arterial ulcer (Figure 2.3).



Figure 2.3: Types of lower extremity ulcers a) Neurotrophic ulcer b) Venous stasis ulcer c) Arterial ulcer [14]

Neurotrophic ulcers or diabetic ulcers are typically caused by prolonged pressure or trauma to the foot. These ulcers mostly located at increased pressure points on the bottom of the foot [15]. Venous stasis ulcer is the end result of venous hypertension [6]. These ulcers often located below the knee, just above the ankle [15]. Arterial ulcers is caused due to poor circulation at the superficial femoral and popliteal vessel [6]. These ulcers often located on the heels, tips of toes or anywhere the bones may rub against each other [15].

2.3.2 Classification of Diabetic Foot Ulcers

There are basically two commonly used classification systems to classify the severity of DFU. DFU can either be classified either by using the Meggit-Wagner classification or University of Texas classification [2, 16].

The Meggitt-Wagner classification is a classification that is based on the wound depth, presence and infection location [16, 17] (Figure 2.4). Its grades ranges from 0 to 5. The first three grades are based on the depth of lesion through soft tissue and the last three grades are based on the extent of foot infection [16, 17].

Wagner classification of diabetic foot ulcers			
Grade 0	Grade 1	Grade 2	
No ulcer in a high-risk foot	Superficial ulcer	Deep ulcer, penetrating down to	
	involving the full skin	ligaments and muscle, but no	
	thickness but not	bone involvement or abscess	
	underlying tissues	formation	
		70	
Grade 3	Grade 4	Grade 5	
Deep ulcer with cellulitis	Localized gangrene	Extensive gangrene involving the	
or abscess formation, often		whole foot	
with osteomyelitis			
		MD:A.N.	

Figure 2.4: The Wagner classification of diabetic foot ulcers [17]

Meanwhile, the University of Texas classification is a classification that is based on the wound depth, presence of infection and presence of ischemia [16, 17] (Figure 2.5). Its grades ranges from 0 to 3.

	Grade/ Depth "How deep is the wound?"					
		0	$0 \qquad 1 \qquad 2 \qquad 3$			
		Pre or post	Superficial	Wound penetrating	Wound	
	А	ulcerative lesion	wound not	to tendon or	penetrating to	
		completely	involving	capsule	bone or joint	
		epithelialized	tendon, capsule			
			or bone			
or both?"			-		(Aa	
ies		With infection	With infection	With infection	With infection	
tage/Comorbiditi nd infected, ische	В	- ALE		P	200	
non		With Ischemia	With Ischemia	With Ischemia	With Ischemia	
"Is the v	C	No.	1	and the second	-	
		With infection	With infection	With infection and	With infection	
		and ischemia	and ischemia	ischemia	and ischemia	
	D	All	6 M)	a	Sil	

Figure 2.5: The University of Texas classification of diabetic foot ulcer [17]

While each system uses a different approach to classify a wound, there is a common between these classifications. For both classifications, the risk of amputation with a longer healing time increases with the grade increment. Regardless of which classification system is used, it is crucial that the system to be used is consistent across the healthcare team and be recorded appropriately in the patient's records [18].

2.4 Gait Cycle

One of the most frequent used forms of the human locomotion during daily activity is gait. A gait cycle is defined as the period from the heel contact of one foot to the next heel contact of the same foot [19]. The gait parameters are essential to be analyzed as it provides the evaluation and characterization of able-bodied and pathological gait, particularly DFU [20].

2.4.1 Phases of a Gait Cycle

The gait cycle is fundamentally comprises of two phases which is the stance phase and swing phase [21] (Figure 2.6). The stance phase is subdivided into five sub-phase namely heel strike, foot flat, heel rise, push-off and toe-off. Meanwhile the swing phase is divided into three sub-phase namely acceleration, toe clearance and deceleration phases.

		Stance Phase		
Heel strike	Foot flat	Heel rise	Push-off	Toe-off
0%	15%	30%	45%	60%



b)

Figure 2.6: The phases of a gait cycle a) Sub-phases of stance phase b) Sub-phases of swing phase [21]

In a normal gait cycle (Figure 2.7), the stance phase accounts for 62%, during which the both of the feet is in contact with the ground and bears the full weight of the body. In the other hand, the swing phase comprises the remaining 38% of the gait cycle and begins at the toe off of the foot. During this phase the foot is off the ground and swinging forward to begin the next stance, while the body weight is transferred to the other foot. On average, this cycle has a duration of one second with 60% on the stance phase and 40% on the swing phase [19].



Figure 2.7: The normal gait cycle of human during locomotion [21]

2.4.2 Plantar Pressure

Plantar pressure has been universally accepted as a vital biomechanical parameter to evaluate human walking [8]. The magnitude and distribution of plantar pressure provides essential information to diagnose various foot disorders, including DFU.

In the foot flat stance phase of a human's gait cycle, both of the feet are in contact with the ground and bears the full weight of the body [20] (Figure 2.8). The feet during this phase thus have the highest plantar pressure.



Figure 2.8: In-shoe plantar pressure measurement for a full gait cycle (right heel strike to right heel strike). HS = heel strike, FF = foot flat, MSt = midstance, HO = heel off, TO = toe off, IS = initial swing, MSw = midswing. [20]

Recent studies indicate that the plantar pressure is highly correlated with the ulcer formation [8]. A higher plantar pressure thus leads to a higher probability of ulcer to form. It indicates that DFU is likely to form at the metatarsal region and heel region since these regions have the highest plantar pressure (Figure 2.9).



Figure 2.9: Location of DFU a) Plantar pressure distribution of a human foot [22] b) Ulcer at 1st metatarsal region c) Ulcer at heel region

2.4.3 Plantar Pressure Measurement

The measurement of plantar pressure during standing, walking or other activities is important as the information from this measurement provides essential support in the assessment of various foot pathologies which includes rheumatoid arthritis, Parkinson's disease and diabetes [20].

There is a variety of plantar pressure measurement systems available on the market but in general they can be classified into two types which are the platform systems and the in-shoe systems [23] (Figure 2.10). Both of these systems have their own advantages and disadvantages. However, they also shared a commonality in that they utilize pressure sensors which are usually comprises of capacitive, piezoelectric, piezoresistive and resistive sensors.



Figure 2.10: Pressure sensing technologies a) Platform systems b) In-shoe systems [23]

Platform systems are constructed from a flat, rigid array of pressure sensing elements arranged in a matrix configuration. These systems are often embedded into the floor or walkway for the analysis of barefoot pressure. Although these systems can be used for both static and dynamic studies, but are typically restricted to research laboratories [23]. The advantage of these systems is the platform is easy to use because it is stationary and flat. The disadvantage of these systems is the patient requires the familiarization with the system to ensure a reproducible natural walking pattern is obtained.

In-shoe systems include sensing elements in the insole and have gained an advantage over platform systems due to their portability. Moreover, these systems has the ability to measure and analyse sequential steps since the foot and the sensors are remain to be aligned together [20]. In the other hand, these systems have the possibility of sensor slipping and the spatial resolution of the data is lower compared to platform systems since these systems comprises of fewer sensors.

2.5 Finite Element Method of the Foot

With the advancement of technology, computational modelling such as finite element (FE) method is an essential tool to enhance the knowledge in foot biomechanics. This is because FE analysis able to predict the distribution between the foot and supports [24]. In addition of providing information on the internal stress and strain states of the ankle-foot complex, they also enable efficient parametric evaluation to be made for the outcome of insole material modifications without needing to fabricate and test orthoses in a series of patient trials.

2.5.1 Recent works on FE of the Foot

Genuinely, FE models of the foot have been developed, based on certain assumptions. These assumptions includes simplified geometry, limited relative joint movement, ignorance of certain ligamentous structures, and also simplified material properties.

FE models are also analyze under assumptions of linear material properties, infinitesimal deformation, and linear boundary conditions, with the consideration of friction and slip condition [25]. However, certain FE models are analyze without the consideration of friction and slip condition [26]. In the other hand, recent models have improved in sleected aspects by incorporating geometric, material or boundary non-linearity. The FE models are analyze under the assumptions of hyperelastic material properties and include the consideration of frictional contact condition [27].

Moreover, the loading conditions are different for each FE models. Some FE models applies a downward pressure on the face generated on tibia and fibula which is chosen as the representation of the downward force of human weight and define the ground surface as the fixed support [25]. There is also FE model which applies a vertical upward force at the Centre of Pressure (COP) of the inferior surface of the ground support [26]. The COP is located about 90 mm from the posterior extreme of the foot and 30 mm from the medial heel extreme. This FE model also fix the superior surface of the soft tissue, distal tibia and fibula. Furthermore, there is also FE model that applies a five equivalent force vectors representing the Achilles tendon tension at the points of insertion, a ground reaction force at the ground support and also fix the superior surface of the soft tissue, distal tibia and fibula [27].

2.5.2 Generation of 3D Foot Models

Generally, foot models are developed using medical imaging techniques which is by using Computed Tomography (CT) scanner [28] (Figure 2.11). With this technique, the foot modelling have improved in selected aspects by incorporating geometric, material, or boundary non-linearity such as large model deformation, nonlinear material properties and slip/friction contact conditions. This method however is time consuming and emits radiations to subject.



Figure 2.11: Foot modelling using medical imaging techniques [29]

A 3D surface scanning method also provides an accurate and repeatable digital representations of the foot shape (Figure 2.12). It is proven to be used successfully in medical, ergonomic and footwear development applications [30]. Hence, 3D scanning method thus provides an alternative yet effective method in developing the foot model.



Figure 2.12: Foot modelling using 3D surface scanning method [31]

2.6 Treatment for Diabetic Foot Ulcer

Lower limb amputation is the most feared consequence for diabetic patients [5]. However, a proper treatment of the DFU reduces this risk. This is because a proper treatment able to promote wound closure and thus prevent its recurrence. There are many principles of treatment for DFU. Wound care, treatment of infection and off-loading are some of the way to treat DFU. However, the off-loading method is known to be the effective tool for managing DFU [32].

2.6.1 Off-loading Techniques

Off-loading techniques involves the reduction of pressure to the DFU. Reduction in pressure reduces the trauma to the ulcer and allows it to heal. This is a crucial component of ulcer healing. However, this method depends on the potential compliance of the patient, the location and the severity of the ulcer, as well as the physical characteristic of the patient [33]. The methods of off-loading includes foot orthosis, total contact cast and rear foot off-loading shoe (Figure 2.13).



Figure 2.13: Different types of off-loading techniques a) Foot orthosis [34] b) Total contact cast [35] c) Rear foot off-loading shoe [36]

2.6.2 Insole of Foot Orthosis

Patients suffering from DM with elevated peak loading pressure and increased soft tissue strain are at higher risk of developing foot ulcers. Hence, they are recommended to wear therapeutic footwear, particularly foot orthosis. A footwear orthosis can be described as a shoe insert that able to off-load pressure in areas of the foot that may cause ulceration. These orthoses can be fabricated from a variety of commercially available materials which possess different degrees of hardness, control and conformability

The primary principle design features for a foot orthosis usually includes the thickness of the insole and the materials used for the insole [5]. An increased in insole thickness will increases the contact area and reduced the localized contact pressures of the foot. However, this effect has its own threshold. This effect reach a plateau when insoles becomes very thick (greater than 12.7 mm) [5]. Hence, an insole of 12.7 mm thickness produced the most effective outcomes in reducing peak plantar pressure for diabetic individuals.

The material used for foot orthosis need to be effective in reducing the general loading pressure across the whole foot. This will effectively lead to a decrease in the average pressure experienced across a foot step throughout the stance phase of the gait cycle, thus reducing the incidence of foot ulceration [37]. Foot orthoses are usually developed using commercially plethora of cushioning materials. There are two popular and soft materials used in podiatric practice, namely Poron and Plastazote [38] (Figure 2.14).



Figure 2.14: Two commonly used materials for developing foot orthoses a) Plastazote foam [39] b) Poron foam [40]

Poron is an open cell polyurethane foam with a hardness of 15-35° Asker C [41]. It is resilient and is able to attenuate repetitive compressive stress and shear. Hence, it has been recommended to be used in the fabrication of foot orthoses as it prevent plantar ulceration [42]. Moreover, Poron too exhibited high energy absorption which could absorb humidity produced inside the shoe and is resistant to perspiration [41]. This features thus make Poron the best candidate to be used in cushioning applications (Figure 2.15).



Figure 2.15: The performance of Poron in cushioning application

In addition, laboratory tests have proven that pure Poron flat insole is able to reduce the peak plantar pressure of the foot by 30-39% [38, 42]. However, the disadvantage of using open cell materials is they will eventually deform and bottoming out [36].

Meanwhile, Plastazote is a closed cell polyethylene material with hardness between 40° and 75° Asker C [41]. Naturally, material with a softer Asker index which is Poron, would be more accustomed to cushion the loading foot for a larger pressure reduction when used as simple insole. However, Plastazote is proven to be more resilient and thus would be more ideal for durability and contouring to the shape of the foot for sustained reduction over time [38]. Moreover, it possess shock absorptive qualities, provide protection, and possess stability or memory properties [36]. In addition, laboratory tests also proved that Plastazote insoles able to reduce the peak plantar pressure by 32-48%, but such insoles must be contoured to the foot so that the surface area would be increased [43].

Chapter Three: Research Methodology

3.1 Introduction

The project began with the preparation of human foot sample by the creation of mould of human foot sample using alginate powder and the creation of sculpture of the human foot sample using Plaster of Paris powder. The sculpture then was tied to the stand of the 3D Scanner for the 3D scanning process. The image obtained from the 3D scanning process was then saved in .igs format for the generation of digital model of the foot which was done using CATIA V5R21. The created digital model was imported into SolidWorks 2014 for the generation of 3D models. The generated 3D models were then used for the Finite Element (FE) Analysis using ANSYS 16.0.

3.2 Sample Preparation

The preparation of human foot sample comprises of two stages which is the mould creation stage and the sculpture creation stage. A sample of human foot was prepared because the 3D scanner was found to able to capture more detailed image of the scanned object when the scanned object was placed on the stand of the 3D Scanner.

3.2.1 Creation of a Mould

A container that able to fit entirely the right foot sample, a 7 oz plastic cup, a cup filled with one litre of water and a disposable teaspoon were first prepared. In addition, 500 g of alginate powder was also prepared (Figure 3.1). An alginate powder was used because it is a liquid gel that can flow over and into the finest of detail which allows it to capture the complex shape of the foot. In addition, it is also one of the most popular yet reliable materials for moulding.



Figure 3.1: The use of alginate powder in the mould creation stage to capture the complex shape of foot [44]

By using the 7 oz plastic cup, it was poured into the container, followed by tap water. The amount of water to be added to the alginate was based on the instruction given by the supplier. The level of the mixture in the container was first evaluated (level above the ankle) before it was mix evenly using the disposable tablespoon. When the mixture was noticeably loses its pink colour, the right foot sample was submerged into the container, after it was wetted with tap water. Next, the toe was wriggled to allow the alginate to fill the entire area of the skin. The mixture was then evaluated to be not sticky when it was touched and cannot be poked. The right foot sample was continued to wriggle until the foot was completely out from the hole, thus preventing damage to the mould. The mould was then left to dry for 2 hours (Figure 3.2).



Figure 3.2: The created mould of the right foot sample to be used in the creation of the foot sculpture

3.2.2 Creation of a Sculpture

A large, empty container, a disposable teaspoon and a cup filled with 1 litre of water were first prepared. A 1 kg of Plaster of Paris powder was also prepared (Figure 3.3). The Plaster of Paris powder genuinely is soft and has the ability to set itself well. This two criteria thus make it the best choice in creating sculptures.



Figure 3.3: The use of Plaster of Paris powder to create the sculpture of human foot sample [45]

The powder was first poured into the container using the disposable teaspoon, followed by tap water. The amount of water to be added to the powder was based on 2 cup of Plaster of Paris to 1 cup of tap water ratio. Next, the mixture was stir slowly and consistently for 2 minutes. The mixture was then evaluated to have the consistency of paint and run easily off the spoon and any excess water in the mould was removed. It was then poured into the mould until the entire mould was filled up. The mixture was left for 4 hours before it was carefully peeled off. The foot sculpture was thus obtained and was left to dry for several days in a well ventilated area. The foot sculpture has an approximate height of 230 mm and width of 90 mm (Figure 3.4).



Figure 3.4: The foot sculpture of the right foot sample which has a dimension of 90 mm width and 230 mm height

3.3 3D Scanning

The 3D scanning was performed by using a Next Engine Desktop 3D Laser Scanner. A personal computer (PC) with operating system of either Window 7 or Window 8, 2.5GHz Quad Core processor, 16GB RAM, and 40GB drive is the minimum system requirement to be able to use its software. The typical hardware parts used in the 3D scanning process were the 3D scanner, the stand, and the rotating platform (Figure 3.5). This scanner able to scan objects by using 3 features which is 360 degree, 180 degree (bracket) and single. Both 360 degree and 180 degree features requires the use of the stand and rotating platform. Meanwhile, the single feature able to scan object at its planar surface only. In this project, the 180 degree feature was selected as the region of interest was the sole of the foot sculpture.



Figure 3.5: Components available in the Next Engine Desktop 3D Scanner